

1                               FEDERAL TRADE COMMISSION  
2                               I N D E X (PUBLIC RECORD)  
3  
4     WITNESS:   DIRECT       CROSS     REDIRECT     RECROSS  
5     Banker     5201         IC  
6  
7     EXHIBITS               FOR ID             IN EVID  
8     Commission  
9     None  
10    Schering  
11    None  
12    Upsher  
13    None  
14  
15    OTHER EXHIBITS REFERENCED             PAGE  
16    Commission  
17    CX 12                                 5210  
18    CX 1663                                5234  
19    Schering  
20    SPX 1270                               5201  
21    SPX 1271                               5203  
22    SPX 2258                               5207  
23    Upsher  
24    None  
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FEDERAL TRADE COMMISSION

In the Matter of: )  
SCHERING-PLOUGH CORPORATION, )  
a corporation, )  
and )  
UPSHER-SMITH LABORATORIES, ) File No. D09297  
a corporation, )  
and )  
AMERICAN HOME PRODUCTS, )  
a corporation. )  
-----)

Monday, February 25, 2002

9:30 a.m.

TRIAL VOLUME 22

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

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1 P R O C E E D I N G S

2 - - - - -

3 JUDGE CHAPPELL: Good morning, everyone.

4 ALL COUNSEL: Good morning, Your Honor.

5 JUDGE CHAPPELL: Anything to handle before we  
6 get started with the witnesses?

7 MS. BOKAT: May I raise one question, Your  
8 Honor?

9 JUDGE CHAPPELL: Yes.

10 MS. BOKAT: About post-trial briefing?

11 JUDGE CHAPPELL: Okay.

12 MS. BOKAT: I was wondering as to findings,  
13 sometimes in the past I've worked on cases where both  
14 sides submitted findings, and then there was an  
15 opportunity for reply findings. So, I wanted to raise  
16 the question of whether that's the way we will be doing  
17 it here, because it will influence the way we write the  
18 findings that everybody's in the process of doing now  
19 to know whether or not there will be any reply  
20 findings.

21 JUDGE CHAPPELL: I don't have a problem with  
22 reply findings if we have time for reply findings. I  
23 envision all sides filing their post-trial brief at the  
24 same time, and then everyone could reply, respond,  
25 whatever you want to call it, within a certain amount

1 of time. So, if we have time, yes, we will do that.

2 MS. BOKAT: Okay, thank you, Your Honor.

3 MR. NIELDS: Good morning, Your Honor.

4 JUDGE CHAPPELL: Good morning.

5 MR. NIELDS: The witnesses on for today are  
6 Dean Banker and Mr. Miller, who will be testifying  
7 about the patent issues in the Upsher case. Pursuant  
8 to agreement amongst the parties, we plan to try the  
9 abbreviated form that I think we mentioned to the Court  
10 earlier. Each witness will have a -- has prepared a  
11 written direct, which complaint counsel has reviewed.  
12 Both parties believe that the written directs that  
13 we've agreed on conform to Your Honor's earlier  
14 rulings.

15 JUDGE CHAPPELL: Okay, and this will be offered  
16 as a joint exhibit or as an exhibit with no objection?

17 MR. NIELDS: No, I think it's an exhibit, no  
18 objection, is my understanding.

19 MR. NOLAN: Yes, no objection.

20 MR. NIELDS: It will be our -- it will be the  
21 direct testimony, and then we've agreed on a maximum of  
22 15 minutes of sort of summary direct that will be  
23 delivered actually from the witness stand by the  
24 witnesses, and then there will be live cross and  
25 redirect. So, that's the format.

1 JUDGE CHAPPELL: Right, and I thought about  
2 your proposal to submit direct in writing, and that's  
3 fine, as long as there's no objection, then it's part  
4 of the record and it's submitted into evidence like any  
5 other evidence. So, that will -- procedurally we can  
6 do it that way.

7 MR. NIELDS: Excellent. We're hoping that that  
8 will save some time, and we're hoping that that will  
9 permit us to get the two witnesses on and off before  
10 our early adjournment this afternoon. If we beat that  
11 time, so much the better. If we don't, I guess it will  
12 have to spill over until tomorrow, but again, we're  
13 hopeful that we can complete these two witnesses today  
14 under this abbreviated format.

15 JUDGE CHAPPELL: The testimony you're  
16 submitting, is it in question and answer format or is  
17 it narrative like a paragraph? How are you doing it?

18 MR. NIELDS: Paragraphs. It's narrative, Your  
19 Honor, like paragraphs. Then, of course, the  
20 abbreviated 15 minutes of live direct will be in  
21 question and answer format, just like a regular  
22 testimony would be.

23 JUDGE CHAPPELL: Okay.

24 MR. NIELDS: One other thing I should mention,  
25 Your Honor, we will be -- by "we," I mean Schering --

1 will be filing a brief memorandum addressing the  
2 relevance of this proof, the proof about the merits of  
3 the underlying patent cases, for the --

4 JUDGE CHAPPELL: Right, the legal opinions of  
5 patent experts issue.

6 MR. NIELDS: That and also just the relevance  
7 of this kind of evidence in this particular case. Your  
8 Honor indicated that you'll reserve the judgment  
9 ultimately on whether and how you will consider this  
10 evidence, and we thought it would be helpful to file a  
11 memorandum which the Court -- we will probably get it  
12 done by the end of today, which the Court can consider  
13 at the appropriate time.

14 Okay, I'm advised it may not be by the end of  
15 today, but we will be filing it very shortly.

16 JUDGE CHAPPELL: Well, and I think I instructed  
17 the parties that it needs to be no later than the  
18 post-trial brief, and the way that was kind of sprung  
19 on me early on a Monday or Tuesday morning, I wanted to  
20 make sure everybody had a chance to brief that issue.  
21 So, there is no rush, Mr. Nields, and also the  
22 Government has the right to rebut.

23 MR. NIELDS: Absolutely.

24 JUDGE CHAPPELL: But since I had asked for it  
25 in post-trial briefs, if it's not done until then,



1       that's okay also.

2               MR. NIELDS:   Fine, thank you very much, and  
3       again, Mr. Lavelle will be calling these two witnesses,  
4       Your Honor.

5               JUDGE CHAPPELL:   Okay, let's begin.

6               MR. LAVELLE:   Good morning, Your Honor.  
7       Schering would call Dean Gilbert Banker to the stand.

8               JUDGE CHAPPELL:   Good morning.  
9       Whereupon--

10                       GILBERT S. BANKER  
11       a witness, called for examination, having been first  
12       duly sworn, was examined and testified as follows:

13               JUDGE CHAPPELL:   Thank you, have a seat.  
14               Please state your full name for the record.

15               THE WITNESS:   Gilbert Stephen Banker.

16               JUDGE CHAPPELL:   Thank you.

17                       DIRECT EXAMINATION

18               BY MR. LAVELLE:

19               Q.   Good morning, Dean Banker.

20               A.   Good morning.

21               Q.   Dean Banker, would you please turn to Schering  
22       Exhibit SPX 1270.

23               A.   Yes, sir.

24               Q.   And would you tell us what that document is?

25               A.   That's my witness statement.

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1 Q. Okay. Who wrote your witness statement?

2 A. I did.

3 Q. Okay. When was it written?

4 A. I believe it was 1996.

5 Q. Okay. And in what circumstances was the  
6 substance of it written?

7 A. It was written in connection with the  
8 Schering/Upsher-Smith litigation.

9 Q. Okay. And now SPX 1270 (sic), you just signed  
10 that this morning, correct?

11 A. Yes.

12 JUDGE CHAPPELL: Excuse me, Mr. Lavelle, sorry.

13 It just occurred to me with the witness  
14 summaries or witness direct that are being submitted  
15 by -- I don't know if by the Government but by the  
16 parties, is it possible to make sure there is nothing  
17 in camera referred to in those exhibits?

18 MR. LAVELLE: Yes, Your Honor, there is nothing  
19 in camera referred to in those exhibits.

20 JUDGE CHAPPELL: Thank you. Sorry to interrupt  
21 you. You may proceed.

22 MR. LAVELLE: Oh, not at all, and that is true  
23 of the Miller one, as well.

24 BY MR. LAVELLE:

25 Q. For the record, I apologize, the witness

1 statement is SPX 1271 and not 1270.

2 And again, 1271 are your words. Is that right?

3 A. They are.

4 Q. Okay, fine, thank you, sir.

5 Did you read SPX 1271 before you came on the  
6 stand?

7 A. I did.

8 Q. And does it reflect your views today as well as  
9 at the time of the Upsher case?

10 A. It does.

11 Q. Are you prepared to adopt Exhibit 1271 as your  
12 direct testimony in this case?

13 A. I am.

14 Q. Okay.

15 Your Honor, I offer Schering Exhibit SPX 1271  
16 into evidence.

17 MR. NOLAN: No objection, Your Honor.

18 MR. CURRAN: No objection, Your Honor.

19 JUDGE CHAPPELL: SPX 1270 is admitted.

20 MR. LAVELLE: I'm sorry, Your Honor, I  
21 misspoke, it's 1271.

22 JUDGE CHAPPELL: Okay, 1270 has not been  
23 offered and is not admitted. SPX 1271 -- any objection  
24 to 1271?

25 MR. CURRAN: No, Your Honor.

1 MR. NOLAN: No, Your Honor.

2 MR. CURRAN: Although perhaps I should add, we  
3 are going to review this to make sure that we are  
4 comfortable that there is no Upsher-Smith material in  
5 there that might warrant in camera treatment. We are  
6 doing that immediately.

7 JUDGE CHAPPELL: Okay, thank you, just let us  
8 know. Are you wanting to withhold then until you have  
9 a chance to review and have him re-offer it later?

10 MR. CURRAN: Well, I can tell you we are not  
11 going to object to its admissibility. It's strictly a  
12 question of in camera status or not.

13 JUDGE CHAPPELL: Mr. Lavelle, why don't you  
14 re-offer that at any point in time, later today's fine,  
15 so that if he has an objection that can be cleaned up,  
16 let's just have one exhibit. We have got a lot of  
17 exhibits in this case.

18 MR. LAVELLE: We would be happy to do that,  
19 Your Honor.

20 JUDGE CHAPPELL: Okay, thank you.

21 MR. CURRAN: Thank you, Your Honor.

22 BY MR. LAVELLE:

23 Q. Dean Banker, at some point in time, were you  
24 retained by Schering to work on the Upsher litigation?

25 A. I was.

1 Q. And about when was that?

2 A. Oh, late 1995, sometime in '95, fall, winter.

3 Q. Before you were retained by Schering, were you  
4 contacted by Upsher regarding whether or not you could  
5 work for them in the Upsher case?

6 A. I was contacted by a Mr. Haas, who was the  
7 attorney representing them.

8 Q. Would you tell the Court what happened when you  
9 were contacted by Upsher's attorney?

10 A. Mr. Haas briefly outlined the situation, the  
11 case, asked me if I would consider representing them or  
12 serving as an expert witness. I did as I normally do,  
13 asked him to send me some background on the case to  
14 review before I gave an answer, which he did.

15 Q. And did you review that material?

16 A. I did. It took me a couple weeks, because I  
17 was traveling and there were a few things I wanted to  
18 look up, but I did review it.

19 Q. And did you then respond to Upsher?

20 A. Yes, I spoke to Mr. Haas, and I believe I may  
21 have also sent him a letter, and I had to decline  
22 taking the case on.

23 Q. And would you explain why you would not take  
24 Upsher's side of the case?

25 A. It was apparent from the materials that were

1 sent that the issue of sorbitan monooleate, whether a  
2 plasticizer or not a plasticizer was at issue, and I  
3 think it was apparent that it was Upsher's contention  
4 that it was not a plasticizer, but I had published  
5 several papers in which I indicated sorbitan monooleate  
6 was a plasticizer, and the fatty acid esters, of which  
7 sorbitan monooleate is one, as a class were  
8 plasticizers, so I didn't feel I could take the case.

9 Q. Were you later contacted by Schering?

10 A. Yes, I was.

11 Q. And did you agree to work for Schering?

12 A. I did.

13 Q. Okay. Do you --

14 A. After -- after letting Schering know that I had  
15 been contacted by Upsher, in the event that would rule  
16 me out as a possible witness.

17 Q. Do you recall the Upsher case was pending in a  
18 Federal Court in New Jersey?

19 A. I do.

20 Q. And that it was filed in late 1995?

21 A. Yes.

22 Q. And do you recall that it was settled in about  
23 June of 1997?

24 A. I do.

25 Q. Where were you when the case settled?

1 A. In a hotel waiting to testify the next morning.

2 Q. In the Upsher case?

3 A. Yes.

4 Q. Okay. Do you recall what the product was in  
5 the Upsher case that was at issue?

6 A. Klor Con M20 was the Upsher-Smith product.

7 Q. Okay. And what was the active ingredient?

8 A. Potassium chloride.

9 Q. Okay. And what was the dosage form of the Klor  
10 Con product?

11 A. A coated potassium chloride crystal which was  
12 compressed into a tablet to be administered orally with  
13 the potassium chloride crystals to be released quickly  
14 in the stomach for distribution throughout the gut in a  
15 sustained release fashion to avoid GI lesions.

16 Q. And what was the amount of the dose in the  
17 Upsher product?

18 A. Twenty milliequivalents or one and a half  
19 grams.

20 Q. And what was the principal component of the  
21 coating of the Upsher product?

22 A. Ethylcellulose.

23 Q. Thank you.

24 Sir, would you turn to SPX 2258, please.

25 A. Yes, sir.

1 Q. Did you help prepare this claim chart, sir?

2 A. I did.

3 Q. Does 2258 represent your views on the  
4 comparison of the Upsher product to claim 1 at the time  
5 of the Upsher litigation?

6 A. It does.

7 Q. The left-hand side of this chart are the  
8 elements of claim 1 of the '743 patent, correct?

9 A. That's correct.

10 Q. And this is the same patent that was at issue  
11 in the ESI case?

12 A. That's true.

13 Q. Can I walk you through this claim, and you tell  
14 me your analysis of whether each element was present?

15 A. Certainly.

16 JUDGE CHAPPELL: I think we have an objection.

17 MR. CURRAN: Your Honor, may I take a moment to  
18 confer with Mr. Lavelle as to in camera treatment of  
19 this demonstrative exhibit, and may I ask that the  
20 demonstrative be taken off the screens while we do  
21 that?

22 JUDGE CHAPPELL: Yes, you may.

23 MR. CURRAN: Thank you.

24 (Counsel conferring.)

25 MR. CURRAN: Your Honor, I move that this



1 testimony, to the extent it reveals the details of  
2 Upsher-Smith's formulation, be taken in camera.

3 MR. LAVELLE: No objection from Schering, Your  
4 Honor.

5 MR. NOLAN: No objection, Your Honor.

6 JUDGE CHAPPELL: So, this testimony is arising  
7 from documentary evidence that has previously been  
8 granted in camera status?

9 MR. CURRAN: Yes, Your Honor.

10 JUDGE CHAPPELL: Okay, I need to ask the public  
11 to leave the courtroom. We are going to move into in  
12 camera session. You'll be notified when the public  
13 session begins. Thank you.

14 (The in camera testimony continued in Volume  
15 22, Part 2, Pages 5253 through 5262, then resumed as  
16 follows.)

17 MR. NOLAN: Your Honor, we've conferred with  
18 Upsher's counsel, and it appears that particular  
19 references to particular aspects of its product may  
20 involve trade secret protection. So, I believe I was  
21 mistaken in terms of saying we could go back onto the  
22 public record, having conferred with -- and I will  
23 apologize and request that we go back to in camera  
24 treatment.

25 MR. CURRAN: I join in that request, Your

1 Honor. Thank you.

2 JUDGE CHAPPELL: My apologies to the public,  
3 but I am going to have to ask you to leave. We have to  
4 go into in camera status. You will be notified when we  
5 go back on the public record. Thank you.

6 (The in camera testimony continued in Volume  
7 22, Part 2, Pages 5263 through 5307, then resumed as  
8 follows.)

9 BY MR. NOLAN:

10 Q. Let's refer to the '743 patent, if we could,  
11 and that's our Exhibit 12, I believe, CX 12.

12 A. I have it.

13 Q. We'll try to move along without actually having  
14 you to see the page unless there's a need to, and if  
15 you need to refer to a particular page or want to see  
16 it on the screen, just let me know.

17 The '743 patent claims a coating material of  
18 ethylcellulose and HPC or PEG, correct?

19 A. Correct.

20 Q. And it's this coating material that achieves a  
21 sustained release of potassium chloride in a tablet?

22 A. Correct.

23 Q. The '743 patent refers to a proper balance of  
24 EC to HPC being required, correct?

25 A. Correct.

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1           Q. And just so we can bring that out for a second,  
2 if we could, Nicole, please turn to column 4, the  
3 second paragraph. It's the, "By providing a proper  
4 balance," if we could just bring that up.

5           "By providing the proper balance of the  
6 ethylcellulose to the hydroxypropylcellulose a polymer  
7 film can be formed on the seeds which will remain  
8 intact in the stomach (and afterwards) but which is  
9 permeable to gastric fluids, which dissolve and leach  
10 out the potassium chloride contained in the coated  
11 crystals (micro pellets)."

12           Is that the reference to the proper balance  
13 that we're talking about?

14           A. I believe so, or it's one of the references.  
15 There may be others. I don't know without going  
16 through the patent.

17           Q. Now, other than this reference to a proper  
18 balance and to permeability, there -- let me rephrase  
19 the question.

20           There is this specific reference to proper  
21 balance, and it uses the word "permeability." Isn't it  
22 correct that nowhere in the patent does it say that the  
23 purpose of the HPC is to produce a soft polar or  
24 elastic film?

25           A. I think the section here --

1 Q. Sorry.

2 A. -- I think the section you just cited, to one  
3 reading this skilled in the art, polymer film formed on  
4 the seeds which will remain intact in the stomach, that  
5 means the film is still intact after being compressed  
6 into a tablet, because the patent's about a tablet  
7 dosage form, not about administering seeds in a  
8 capsule. So, this clearly conveys to one skilled in  
9 the art that these seeds -- that this film must have  
10 been sufficiently durable to be compressed and to  
11 remain intact and deliver material through the film,  
12 which is permeable to gastric fluid, if that answers  
13 your question.

14 JUDGE CHAPPELL: Do you need a moment to get  
15 those papers organized?

16 MR. NOLAN: I think I'm okay, Your Honor, thank  
17 you.

18 JUDGE CHAPPELL: All right.

19 BY MR. NOLAN:

20 Q. My specific question, Dean Banker, is there's  
21 nowhere in the '743 patent that hydroxypropylcellulose,  
22 that it specifically states that it produced a soft  
23 film, correct?

24 A. No, there's nothing in the patent that says the  
25 word "soft film" that I recall. The patent in the same

1 paragraph clearly defines the micro pellets separating,  
2 not causing irritation, which has other meaning to one  
3 skilled in the art.

4 Q. At your deposition in the original case, you  
5 were asked to point to words that HPC produces a soft  
6 polar elastic film, and all you said was that it's  
7 intuitive, correct, and that it's obvious?

8 A. And that's what I'm saying today.

9 Q. You didn't do any tests to show that HPC is a  
10 plasticizer with respect to ethylcellulose, did you?

11 A. I did some tests, yes.

12 Q. You didn't do any tests to show that HPC is a  
13 plasticizer with respect to ethylcellulose, correct?  
14 HPC.

15 A. HPC, no, I did not.

16 Q. And at the deposition in the original case, you  
17 couldn't cite to any literature that described HPC as a  
18 plasticizer for ethylcellulose, correct?

19 A. I don't recall. That may be true, but such  
20 citations are out there, as I've indicated.

21 Q. When you say it may be true, isn't it true?

22 A. If you have it there, then that's what I said.  
23 I won't deny that that's what I said, but there are  
24 clearly references that so define it.

25 Q. Now --

1 A. Which I might have been unaware of then.

2 Q. -- if I may just have a minute to ask a  
3 question here, there's not a specific question.

4 Just so we can -- the -- refer back to your  
5 deposition for a moment, sir, and particularly this is  
6 page 449, and there's a question, I believe again by  
7 Mr. Haas from Upsher-Smith.

8 "QUESTION: The paragraph --" I'll give you a  
9 moment to look for it. It's on page 449.

10 A. Yes, this is a six-day deposition. It must  
11 have almost set a record.

12 Q. "QUESTION: The paragraph beginning with, 'By  
13 providing the proper balance of the ethylcellulose,' is  
14 that your underscore and star in that?

15 "ANSWER: Yeah, that's my underscore and star.

16 "QUESTION: And what does that paragraph refer  
17 to?

18 "ANSWER: That refers to the fact that by using  
19 the proper balance of these film modifiers, you can  
20 produce desirable permeability in gastric fluids and to  
21 allow dissolving and leaching out of the potassium  
22 chloride. I think that's an important segment, that  
23 that's what these film modifiers are there to produce,  
24 at least in part.

25 "QUESTION: Does that reference refer to the

1 durability of the coating?

2 "ANSWER: No. It's what I just stated it  
3 referred to."

4 Did you give that testimony?

5 A. I'm sure I did if you're reading it accurately.  
6 And it goes on to say they're doing more than one  
7 thing.

8 Q. When we talk about proper balance in the '743  
9 patent, we're talking about that in the context of  
10 achieving a sustained release of the potassium  
11 chloride?

12 A. That's part of it, yes.

13 Q. And is it true that in presenting the argument  
14 for why Schering should be awarded the '743 patent, the  
15 lawyer from Schering, Mr. Maitner, told the patent  
16 examiner that a careful analysis of the Hsiao patent  
17 would not lead one skilled in the art to utilize an  
18 ethylcellulose polymer having a viscosity greater than  
19 40 cp?

20 MR. LAVELLE: Objection, Your Honor, outside of  
21 the scope of the witness' direct. The witness hasn't  
22 testified about the prosecution history, and we have a  
23 patent lawyer expert who those questions can be  
24 directed to, and I think this one is just more  
25 appropriately addressed to Mr. Miller.

1           MR. NOLAN: Your Honor, I simply raise this  
2 part of the cross examination to attempt to bring out  
3 and fully explore technical aspects to relate to the  
4 issue that the court would have had to resolve, which  
5 is whether to accept Dean Banker's characterization  
6 that the polymers, HPC and PEG, were added for  
7 plasticizing or whether they have some other purpose,  
8 and it's my understanding from Dean Banker's  
9 methodology that he reads the prosecution history, and  
10 so for the limited purpose and briefly going through  
11 that, we would request permission to do that.

12           JUDGE CHAPPELL: So, you're testing the  
13 underlying data and assumptions that went into his  
14 opinions?

15           MR. NOLAN: That's correct, Your Honor.

16           JUDGE CHAPPELL: Overruled.

17           Susanne, would you read the question back,  
18 please.

19           (The record was read as follows:)

20           "QUESTION: And is it true that in presenting  
21 the argument for why Schering should be awarded the  
22 '743 patent, the lawyer from Schering, Mr. Maitner,  
23 told the patent examiner that a careful analysis of the  
24 Hsiao patent would not lead one skilled in the art to  
25 utilize an ethylcellulose polymer having a viscosity



1 greater than 40 cp?"

2 BY MR. NOLAN:

3 Q. To produce a sustained release tablet.

4 JUDGE CHAPPELL: Well, let's see if he can  
5 answer the question you asked before you add even more  
6 to it.

7 MR. NOLAN: Okay, okay.

8 THE WITNESS: I don't know.

9 JUDGE CHAPPELL: Now you may proceed.

10 BY MR. NOLAN:

11 Q. If we could just bring up on the screen,  
12 Nicole, it's Bates numbered, of the same CX 12, 21373,  
13 the bottom of the page is number 4. It's in the  
14 original one that we distributed, but this might be an  
15 appropriate time, while you bring it up, to hand out  
16 some of the binders.

17 Your Honor, if I may approach the witness?

18 JUDGE CHAPPELL: Yes.

19 BY MR. NOLAN:

20 Q. If you require any assistance, I can find the  
21 page for you, Dean Banker.

22 A. Okay, please.

23 MR. NOLAN: May I approach the witness, Your  
24 Honor?

25 JUDGE CHAPPELL: Yes.

1 BY MR. NOLAN:

2 Q. We did review this previously in the ESI case  
3 to a certain extent, and I just wanted to --

4 A. Is this part of the file history, is that what  
5 I'm looking at?

6 Q. You are looking at a response here to the  
7 Patent & Trademark Office from John Maitner of Schering  
8 dated March of --

9 MR. LAVELLE: February 27th.

10 BY MR. NOLAN:

11 Q. -- February 27th of 1999 --

12 MR. LAVELLE: '89.

13 BY MR. NOLAN:

14 Q. -- 1989, and I'll read that passage.

15 "A careful analysis of the Hsiao patent would  
16 not lead one skilled in the art to utilize an  
17 ethylcellulose polymer having a viscosity greater than  
18 40 cp and preferably a viscosity of about 85-110 cp to  
19 produce a sustained release potassium chloride tablet."

20 The question, sir, is that the argument is  
21 being presented that this invention relates to  
22 achieving a sustained release through higher  
23 viscosities of ethylcellulose, correct?

24 A. Presumably, just taking this out of context. I  
25 haven't read the whole letter, and I'm not totally

1 familiar with where this is all coming from. It must  
2 have something to do with rejection of claims.

3 Q. And if you would refer to the following page  
4 where it says, "The Examiner's attention is directed to  
5 Example 1 and Table I."

6 A. Okay.

7 Q. If we can bring that up.

8 Without reading all of this text, my question  
9 is, isn't it true that at this point Mr. Maitner is  
10 directing the examiner to examples in the patent?

11 A. I guess he is, and he may be trying to point  
12 out that ethylcellulose 10 doesn't work.

13 Q. And you've seen these examples in the patent,  
14 correct?

15 A. Yes, yes.

16 Q. And he is drawing attention to the fact that  
17 the ethylcellulose 10 does -- as compared to the  
18 ethylcellulose 100 does not achieve the same results.

19 A. It does not. It will provide a controlled  
20 release from the coated crystals, but it won't provide  
21 a controlled -- a good controlled release from the  
22 coated crystals after they're compressed.

23 Q. Okay.

24 A. After they're compressed, they dump about half  
25 their dose in the first hour, which isn't satisfactory,

1 but for the coated crystals, if they get put in a  
2 capsule, they're fine, but the 10 doesn't seem to work  
3 for the tablets.

4 Q. And do you see -- if we could bring up, Nicole,  
5 at the bottom of the page where it says, "The results  
6 reported are clearly unexpected," that sentence.

7 Okay, it states, "The results reported are  
8 clearly unexpected and one skilled in the art would not  
9 expect or predict such results based on the prior art  
10 Hsiao reference."

11 So, isn't it true -- is it true that Mr.  
12 Maitner is pointing out -- do you understand Mr.  
13 Maitner to be pointing out that one would not have  
14 expected that the higher ethylcellulose would achieve a  
15 sustained release?

16 A. I didn't think that was what the tenor of this  
17 was. I think he was relating that to the higher  
18 molecular weight. I thought he was referring to maybe  
19 the finding of the 10. I think in some of the earlier  
20 patents the 10 worked for things like theophylline and  
21 aspirin. So, isn't that what he's referring to here?

22 Q. Let's refer to page 7 of the patent.

23 JUDGE CHAPPELL: Mr. Nolan, I think you're  
24 getting far beyond whether this witness was aware of  
25 this, whether he considered this in forming his

1 opinion. I'm not sure it gets us anywhere to ask him  
2 what he thinks this person meant.

3 MR. NOLAN: Your Honor, the witness testified  
4 the first time he was on the stand that one aspect of  
5 his methodology is to read the prosecution history, and  
6 as a technical expert, reading the prosecution history,  
7 this particular letter is -- I am asking his  
8 understanding to the extent that he has one, which I  
9 think is relevant in the sense that if he doesn't have  
10 an understanding, that may have some bearing on his  
11 analysis as a technical expert.

12 JUDGE CHAPPELL: Okay, as long as you're going  
13 to connect up some relevance here pretty soon.

14 MR. NOLAN: Thank you, Your Honor.

15 BY MR. NOLAN:

16 Q. If we could turn to page 7, Nicole, and it  
17 refers to -- where it says, "There is no teaching --"  
18 it's down below.

19 A. I have it, I have it.

20 Q. "There is no teaching that crystals of  
21 potassium chloride coated with a combination of  
22 polymeric materials containing ethylcellulose having a  
23 viscosity greater than 40 cp would provide a compressed  
24 tablet exhibiting sustained release properties whereas  
25 a similar compressed tablet made from potassium

1 chloride crystals coated with a material containing an  
2 ethylcellulose polymer having a viscosity of 9-10 cp --  
3 11 cp would not exhibit sustained release  
4 characteristics."

5 Would you agree with me that you understand Mr.  
6 Maitner to be directing the patent examiner to the fact  
7 that the higher viscosity achieves a sustained release  
8 in tablets, and that's the teaching of this patent?

9 MR. LAVELLE: Objection, Your Honor, compound  
10 and ambiguous.

11 JUDGE CHAPPELL: I'm going to overrule it. The  
12 witness can either -- it's "would you agree with me  
13 that you understand," so he can clearly say yes or no.  
14 So, I'll overrule the objection.

15 THE WITNESS: Could I have the question back,  
16 please?

17 (The record was read as follows:)

18 "QUESTION: Would you agree with me that you  
19 understand Mr. Maitner to be directing the patent  
20 examiner to the fact that the higher viscosity achieves  
21 a sustained release in tablets, and that's the teaching  
22 of this patent?"

23 THE WITNESS: No.

24 BY MR. NOLAN:

25 Q. Do you agree that EC-10 and HPC does not work

1 in tablets when compressed?

2 A. I'd agree with that.

3 Q. Do you agree that HPC does not sufficiently  
4 plasticize EC-10 to work at the 10 viscosity?

5 A. I don't know, because that's not why EC-10  
6 fails. EC-10 is just inherently a low molecular weight  
7 polymer forming weak forms, which couldn't possibly be  
8 treated to be able to withstand compression.

9 Q. In preparing your expert testimony, sir, did  
10 you review the testimony of Cathy Ku, who is one of the  
11 inventors behind the '743 patent?

12 A. Yes, yes.

13 Q. Did you spend much time reading that?

14 A. At one time I read it pretty thoroughly. I  
15 haven't read it recently.

16 Q. I direct your attention to a portion of her  
17 testimony, on page 82 of her testimony. I'm not sure  
18 you have -- that's not your --

19 A. Okay.

20 Q. -- this is from the binder that we had  
21 originally in the ESI matter. Just with respect to  
22 this brief part, perhaps if we could look at this,  
23 there was a question here:

24 "QUESTION: Was it your understanding that it  
25 had been previously known in other sustained release

1 products that higher viscosity Ethocel are better for  
2 tableting purposes?

3 "ANSWER: My knowledge at that time was nobody  
4 had used K-100 during coating."

5 "QUESTION: In any sustained release  
6 formulation?

7 "ANSWER: I didn't know of any at that time for  
8 fluid bed coating."

9 Do you understand Ms. Ku to be saying that it's  
10 the use of the Ethocel 100 that was novel here in terms  
11 of this particular coating?

12 A. I can't -- I can't adopt that position from the  
13 limited words here. I don't know that that was her  
14 position. I doubt it was.

15 Q. Would you agree with me that the '743 patent  
16 prosecution indicates that much was unknown about the  
17 sustained release properties of ethylcellulose at  
18 different viscosities prior to the '743 patent?

19 A. Did you say much was unknown?

20 Q. Yes.

21 A. About the different viscosities prior to the  
22 '743 patent? I don't know. Without reviewing all of  
23 the publications that existed. I think there was a  
24 fair amount known, especially the work of Rowe, but  
25 it's a vague question.



1           MR. NOLAN: Your Honor, at this point, I'm  
2 going back into some references to confidential  
3 material.

4           JUDGE CHAPPELL: This would be a good time to  
5 break for lunch, and since it's already 11:40, we'll  
6 take a little over an hour, and we're not going to be  
7 able to take a break in the afternoon, just prepare  
8 yourself. So, we'll recess until 12:45.

9           (Whereupon, at 11:40 a.m., a lunch recess was  
10 taken.)

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1 AFTERNOON SESSION

2 (12:45 p.m.)

3 JUDGE CHAPPELL: Mr. Nolan, are you ready to  
4 continue?

5 MR. NOLAN: Thank you, Your Honor.

6 Your Honor, we have a few minutes that I think  
7 is not confidential material, and then we will move  
8 into that, okay?

9 JUDGE CHAPPELL: Okay.

10 BY MR. NOLAN:

11 Q. Dean Banker, in the original patent lawsuit,  
12 you relied on literature from Dow, correct?

13 A. Yes.

14 Q. And in this lawsuit, you also have relied on  
15 Dow literature, correct?

16 A. Yes.

17 Q. And in the original lawsuit, you gave a  
18 statement of -- that was dated back in 1997, a  
19 declaration of Gilbert S. Banker, Ph.D.?

20 A. Yes.

21 Q. And in fact, it was January 9th, 1997. Would  
22 you accept that?

23 A. I would.

24 Q. Okay. And in this declaration --

25 A. Could I have a copy of it, please?

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1           Q. Well, if you like, I'll let you look at this  
2 particular page before we put it up, but this is  
3 something I copied on short notice today.

4           A. Okay.

5           MR. NOLAN: If I may approach the witness?

6           MR. LAVELLE: Well, why don't you let him see  
7 the context, as well. I think that's what he's asking  
8 for.

9           JUDGE CHAPPELL: Yes.

10          MR. CURRAN: Pardon me, may I inquire, Mr.  
11 Nolan, what the CX number is on this?

12          MR. NOLAN: This is not a CX. This is a  
13 declaration that was provided in the original lawsuit,  
14 underlying lawsuit.

15          MR. CURRAN: Okay, I inquire only for in camera  
16 treatment purposes.

17          MR. NOLAN: Um-hum. This portion simply refers  
18 to one point.

19          BY MR. NOLAN:

20          Q. Your position back in 1997 was that, "One of  
21 ordinary skill in the art would distinguish, for  
22 purposes of coating and tableting potassium chloride,  
23 between higher viscosity ethylcelluloses, such as  
24 Ethocel 20, 45 or 100 on the one hand, and lower  
25 viscosity ethylcelluloses, such as Ethocel 4, 7 and 10

1 on the other," correct?

2 A. Correct.

3 Q. And you noted that, "Such a distinction is  
4 explicitly recognized in the Dow product literature"?

5 A. Correct.

6 Q. And that -- you asserted that that literature  
7 recommends only Ethocel 20 and the other higher  
8 viscosity ethylcelluloses for the purposes of  
9 microencapsulation, correct?

10 A. That's correct.

11 Q. And you asserted that back in 1997, correct?

12 A. Yes.

13 Q. I forget the month that I just told you, but --

14 A. I think you said January.

15 Q. January, okay.

16 And in your current witness statement, which I  
17 believe you have in front of you in your own binder,  
18 and in paragraph 28, you've continued to make  
19 essentially the same assertion, correct?

20 A. Correct.

21 Q. Okay. Now, you've relied considerably on the  
22 Dow literature, correct?

23 A. I -- rather than saying "considerably," I would  
24 say to some degree.

25 Q. Do you recall being at a deposition with me?

1           A.   Yes.

2           Q.   And at that deposition, was it your intention  
3   to give the most truthful testimony you could?

4           A.   It was.

5           Q.   And do you recall me asking you this question  
6   on page 117:

7                "QUESTION:  Tell me in general terms to what  
8   extent you rely on the Dow report and what does it mean  
9   to you.

10               "ANSWER:  I rely considerably on the Dow report  
11   for the reasons I've given.  I think it's an important  
12   piece of prior art."

13               Is that your testimony?

14           A.   I agree.

15           Q.   Now, you got this Dow report from Dow  
16   representatives.  Is that your testimony?

17           A.   I don't recall.  I might have picked it up at a  
18   trade show.  I might have received it from a Dow  
19   representative.  I simply don't recall.

20           Q.   You don't know when you first received the  
21   brochure, correct?

22           A.   No.

23           Q.   And you particularly rely upon a chart to --  
24   that relates to the selection of ethylcellulose  
25   products for pharmaceutical applications?

1           A. That's true.

2           Q. And you assert that Chart 2 in the exhibit you  
3       used recommends microencapsulation at 20, 45 or 100  
4       viscosity.

5           A. It suggests for the purposes of  
6       microencapsulation one of those three higher molecular  
7       weight class materials be used, that's true.

8           Q. And you've been wrong about this Dow  
9       recommendation at least since 1996, correct?

10          A. No.

11          Q. You've used a mistaken chart.

12          A. No.

13          Q. You've cited the wrong viscosities Dow  
14       recommended at the time of the original litigation,  
15       correct?

16          A. No.

17          Q. And you knew you were citing out-of-date  
18       literature.

19          A. No.

20          Q. Well, let's look at the transcript in the old  
21       deposition. If you would turn to the big thick  
22       deposition that I gave you earlier, the one from the  
23       original litigation.

24          A. This one?

25          Q. Yes. And turn to page 342 --

1 A. Oh, no, you mean the --

2 Q. That one, I'm sorry. I'll give you a second to  
3 orient yourself a bit.

4 A. Okay, we're on page 342?

5 Q. Correct, and line 24, there's -- there's a  
6 question that says, "Let me mark as Banker Exhibit  
7 Number 12 a multi-page document entitled Ethocel --"

8 A. I go from page -- I'm sorry, I go from page 330  
9 to 343. What page are we on?

10 Q. From 337 to 342.

11 A. I don't have those pages here.

12 Q. Just a moment.

13 A. I go from 336 to 343. There are pages missing.  
14 Oh, here's page 342 on back. There are pages out of  
15 place.

16 Q. Okay. Do you have page 342?

17 A. I do.

18 Q. And 343?

19 A. I go from 342 to 335. Oh, here it is, here it  
20 is.

21 Q. Okay.

22 A. Again, they're out of place.

23 Q. Thank you.

24 I just read the exhibit was being marked, and  
25 then there is a series of questions -- a discussion

1       that takes place. There is -- Banker Exhibit 12 was  
2       marked for identification.

3               "MR. HERMAN: Mr. Haas, is this a document that  
4       you've produced to us before?

5               "MR. HAAS: I don't believe I have, Counsel, I  
6       don't know.

7               "MR. HERMAN: How long have you had this  
8       document, Mr. Haas?

9               "MR. HAAS: That I don't know either.

10              "MR. HERMAN: You obviously had it before  
11       today, didn't you, sir?

12              "MR. HAAS: Obviously.

13              "MR. HERMAN: But you chose not to produce it  
14       to us, is that correct?

15              "MR. HAAS: It's publicly available, Counsel.

16              "MR. HERMAN: Did you produce it to us, Mr.  
17       Haas, yes or no?

18              "MR. HAAS: I don't know.

19              "MR. HERMAN: I'm going to represent to you you  
20       did not, and that's improper, sir."

21              Then the question by Mr. Haas:

22              "QUESTION: Dr. Banker, I'm going to show you  
23       what's Exhibit Banker 12 and ask you to identify it for  
24       me.

25              "MR. HERMAN: Have you ever seen this before,



1 Dean Banker?

2 "ANSWER: No, I haven't.

3 "QUESTION: Does this appear to be public  
4 literature also from Dow, publicly available  
5 literature, similar in nature to that which is attached  
6 in your expert report?

7 "MR. HERMAN: Do you know if it's publicly  
8 available, Dean Banker?

9 "THE WITNESS: I have no knowledge that it is.

10 "QUESTION: Well, if you turn to table two in  
11 Banker Exhibit 12. You see in this document table two  
12 in describing microencapsulation describes Ethocel's  
13 standard 45 or 100 premium?

14 "ANSWER: I see that.

15 "QUESTION: It does not describe Ethocel 20?

16 "ANSWER: No, it does not.

17 "QUESTION: Can you explain why not?

18 "ANSWER: I have no idea.

19 "QUESTION: Did you review this document at any  
20 time before today's deposition?

21 "ANSWER: I haven't seen this document. It was  
22 not presented to me."

23 Sir, you were presented back in this deposition  
24 of March 20th, 1997 with Dow literature that did not  
25 include the Ethocel 20, correct?

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1 A. In 1997?

2 Q. Yes.

3 A. Yes, I was dealing with a Dow literature as of  
4 the time of the patent in the citation of the 20, 45  
5 and 100, and this Dow literature had come out much more  
6 recently. What's the date of that Dow bulletin?

7 Q. We'll get to that. The deposition is March  
8 20th, 1997.

9 A. But my question is, what's the date of the Dow  
10 bulletin that you're referring to?

11 Q. We will get to it.

12 A. Because that must have been well past the date  
13 of the patent.

14 Q. There is no question on the floor.

15 Now, I'd like to show you a 1996 Dow report,  
16 and if I may approach the witness, Your Honor, with  
17 this second group of binders, which we may only use a  
18 little of.

19 JUDGE CHAPPELL: Yes, you may.

20 MR. NOLAN: May I approach, Your Honor?

21 JUDGE CHAPPELL: Yes.

22 BY MR. NOLAN:

23 Q. If you would, sir, turn to CX 1663.

24 A. Okay.

25 Q. Do you see the Table 2 on page Bates 22694?

1 A. Okay.

2 Q. Do you see where it says,

3 "Micro-encapsulation?"

4 A. I do.

5 Q. And where it refers to, "Ethocel Standard 45,

6 or 100 Premium"?

7 A. I do.

8 Q. And that table does not include Ethocel 20,

9 correct?

10 A. Correct.

11 Q. Now, if we could turn to the last page, do you

12 see that it says, the Dow -- this was published in May

13 of 1996?

14 A. Where is that date? I don't see it.

15 Q. It may have been truncated by the copying.

16 A. Yeah, I don't see a date on this.

17 Q. Do you see on the screen here, I'm using the

18 original?

19 A. It says it on the screen, not on my copy.

20 Q. Okay. So, do you see that it -- this exhibit,

21 CX 1663, which is Ethocel Premium Polymers for

22 Pharmaceutical Applications, was published as of May

23 1996?

24 A. Okay.

25 Q. And that would be at least more than six months

1 before you signed your declaration, correct?

2 A. Presumably, yes, but I fail to see the  
3 relevance. I was referring to what was reported at the  
4 time of the patent.

5 Q. It's just a yes or no question.

6 A. Okay, well, I'm explaining my yes or no.

7 Q. That -- this would have been the most  
8 up-to-date Dow literature at the time of the underlying  
9 patent litigation, correct?

10 A. I don't know.

11 Q. In any event, you relied on literature that was  
12 out of date in your report, correct?

13 A. Not at the time of the -- not at the time of  
14 the patent. It was -- this was published long after  
15 the time of the patent.

16 Q. But before the settlement in this case.

17 A. Yes.

18 Q. And while the matter was still being litigated,  
19 correct?

20 A. Presumably.

21 Q. You never made a call to Dow about how they  
22 interpret this document, correct?

23 A. No, I wasn't aware of the document at the time.

24 Q. And you no longer know what Dow's position is,  
25 correct?

1           A. I know that as of February 1998, they list  
2           sorbitan and fatty acid esters as plasticizers, but I  
3           don't know what they list currently for  
4           microencapsulation.

5           Q. If you were just plain wrong relying on  
6           out-of-date Dow literature and Upsher-Smith's attorneys  
7           knew it, it's conceivable that your testimony in the  
8           underlying litigation would have been discounted as  
9           unreliable, correct?

10          A. This, as I've indicated, was only -- and my  
11          answer to that is no, because this is only one piece of  
12          information, as I've indicated. The high molecular  
13          weight grades are discussed, the low molecular weight  
14          grades are discussed. I can agree completely with  
15          Dow's assessment of the 20, 45 and 100 as being high  
16          molecular weight and the other grades being as low  
17          molecular weight. Dow is completely right on that.

18                 I have no idea why they didn't list the 20  
19          here, whether it was an oversight or what. I just  
20          don't know.

21          Q. So, when Dow agrees with your position, you  
22          rely on them, but when they don't, you don't.

23          A. I don't use technical references as my only  
24          source of reliance, and I didn't do that in this case.  
25          It was a piece, but it wasn't the entire piece.

1           Q. Let's talk a little bit more, go back to what  
2 we were talking about before lunch, which is trying to  
3 put together the question of what is equivalent to or  
4 insubstantially different from the ethylcellulose.  
5 Basically, my first question is, in your paragraph 22  
6 of your witness statement in this case, I believe that  
7 you assert that Upsher-Smith's process of making Klor  
8 Con --

9           MR. CURRAN: This is -- I'm sorry, if this is  
10 going to be going into Upsher-Smith's formulation, I'd  
11 request that it be taken in camera.

12          MR. NOLAN: Yes, if we could.

13          JUDGE CHAPPELL: At this time I will have to  
14 ask the public to leave the courtroom. We are going  
15 into in camera session. We will notify you when the  
16 public may re-enter. Thank you.

17           (The in camera testimony continued in Volume  
18 22, Part 2, Pages 5308 through 5356, then resumed as  
19 follows.)

20          JUDGE CHAPPELL: How much more do you think you  
21 have, Mr. Nolan?

22          MR. NOLAN: I think probably 20 minutes, 15-20  
23 minutes.

24          JUDGE CHAPPELL: Okay, proceed.

25          BY MR. NOLAN:

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1           Q. Dean Banker, the Dow literature explains that  
2     by varying the type of Ethocel, the unsoluble versus  
3     soluble, excipient ratio and the coating weight, wide  
4     variations of release rates can be achieved, correct?

5           A. I presume they have something like that in  
6     their literature. They have some formulation  
7     instructions, yes.

8           Q. And you recall that was their -- that was the  
9     known view at the time, that by varying these ratios,  
10    that you could achieve different -- different release  
11    rates?

12          A. I believe that's true.

13          Q. And the Dow Chemical literature which you rely  
14    on has very clearly stated that HPC and PEG are used to  
15    affect the release patterns of EC?

16          A. I believe that's in the Dow literature if not  
17    the Hercules literature.

18          Q. And you would expect a quicker release with a  
19    water-soluble plasticizer than if you used a  
20    water-insoluble plasticizer?

21          A. It depends.

22          Q. The sorbitan -- all right, if I could direct  
23    your attention, sir, to page 484 of your testimony, and  
24    it's line 19. Line 19 of page 483, I'm sorry.

25          A. Okay.

1 Q. There's a question:

2 "QUESTION: Would you expect a quicker release  
3 from using a water soluble plasticizer than if you were  
4 to use a water insoluble plasticizer?

5 "ANSWER: You would -- again, it relates to the  
6 solubility of the -- solubility and water reactivity of  
7 the plasticizer relative to the ethylcellulose."

8 A. And that's exactly my position. It's not just  
9 solubility. It's water reactivity, and sorbitan  
10 monooleate is water-insoluble, but it's highly  
11 water-reactive, as I described earlier, dropping the  
12 surface tension substantially and increasing the  
13 viscosity very materially of a 1 percent aqueous  
14 dispersion.

15 Q. With a high viscosity EC, water-soluble HPC and  
16 PEG may increase the release rates, correct?

17 A. Did you say a higher viscosity ethylcellulose?

18 Q. Let me rephrase my question, it's unclear.

19 With the ethylcellulose 40 and above, the HPC  
20 and PEG might increase the release rates, correct?

21 A. They may.

22 Q. On the other hand, with a lower viscosity EC,  
23 the -- or a water-insoluble ingredient, that might  
24 decrease the release rate, correct?

25 A. Well, if we stick to -- if we stick to one



1 polymer class, what's the effect of increasing or  
2 decreasing the material on release rate, the lower  
3 molecular weight films, the 10, 7, 4, as I've indicated  
4 earlier, are weak films. They're less coherent. They  
5 probably do contain more cracks. And so it's a  
6 compound -- it's a complex question. It's a function  
7 of whether your film modifier is plugging those cracks.  
8 It's a function of whether there are cracks to begin  
9 with. It's -- it's -- as I think I was trying to  
10 answer here, it's not simple.

11 Q. You acknowledge that release rates would vary  
12 depending on which plasticizer you choose to use with  
13 ethylcellulose, correct?

14 A. Yes, the plasticizer can affect the release  
15 rate, but it's not always a case of the water-insoluble  
16 plasticizer decreasing the release rate if the  
17 water-insoluble plasticizer is highly water-reactive.

18 Q. In the original patent, when -- going back and  
19 referring to ethylcellulose, the example only has two  
20 data points, correct, 10 and 100?

21 A. Yes.

22 Q. And claim 1 claims Ethocel 45 and above?

23 A. Yes.

24 Q. Or the -- the inventors didn't study what was  
25 in between 10 and 100?

1           A. You know, I really don't know.

2           Q. Okay. In any event, by looking at the patent,  
3 you wouldn't know what the properties were of  
4 ethylcellulose between 10 and 100, correct?

5           A. You know that 10 won't work to make tablets.  
6 You know that he says at the bottom of column 4, the  
7 last six lines or so, "preferably more than 40," but he  
8 indicates there are useful cellulose designations of 7  
9 and higher. The -- I'll leave it that and wait for  
10 your next question.

11          Q. There's no empirical data, is there, sir, of  
12 what the properties of ethylcellulose 40 or 45 are,  
13 correct, in the patent?

14          A. I missed the question, somebody was coughing  
15 behind you, if you could --

16          Q. Looking at the examples in the patent, there's  
17 no empirical data provided as to the properties of  
18 ethylcellulose 40 or 45, correct?

19          A. I don't believe so.

20          Q. The only ones are 10 and 100, correct?

21          A. That's correct.

22               (The in camera testimony continued in Volume  
23 22, Part 2, Pages 5357 through 5366, then resumed as  
24 follows.) (Retroactive designation. See Volume 22,  
25 Part 1, Page 5243.)

1 JUDGE CHAPPELL: You will need to clean off  
2 your counsel tables.

3 MR. CURRAN: We will, Your Honor.

4 JUDGE CHAPPELL: And I suppose you can  
5 designate one individual to stand by in the courtroom  
6 to let you know, we will reconvene 15 minutes after my  
7 next hearing concludes. So, we're in recess.

8 MR. LAVELLE: Thank you, Your Honor.

9 (A recess was taken, 2:50 p.m. to 5:35 p.m.)

10 JUDGE CHAPPELL: Let's reconvene docket 9297.  
11 Mr. Nolan, you may proceed.

12 MR. NOLAN: Your Honor, while there was a  
13 break, I briefly concurred with Mr. Curran, and we've  
14 got an in camera treatment of the record, and I believe  
15 he would like to make a statement that I have no  
16 objection to.

17 JUDGE CHAPPELL: Okay.

18 MR. CURRAN: Your Honor, I believe that the  
19 transcript shortly before we concluded, we were on the  
20 public record at the time, disclosed some in camera  
21 materials that I'd like to -- and I'd like to move to  
22 have those portions of the transcript put in camera.  
23 In particular, beginning at page 147, line 16 [prior to  
24 repagination], there were questions and answers that  
25 reveal Upsher-Smith's formulation, and I believe Mr.

1 Nolan agrees that those -- that the transcript  
2 beginning at that page through where we took the break  
3 should be placed in camera.

4 MR. NOLAN: Your Honor, I would just add that  
5 the pages Mr. Curran is referring to refer to the  
6 numbers that Dow refers to in its viscosity. There was  
7 no -- I have no objection to putting that in camera,  
8 but I'm not certain that by itself it actually reveals  
9 anything about Upsher's product. I just -- I don't  
10 have an objection, but I do disagree in terms of I  
11 don't believe that -- certainly we didn't intentionally  
12 seek to reveal in camera material.

13 MR. CURRAN: I'm not suggesting any intent.  
14 I'm just suggesting that the questions and answers give  
15 the clear implication of what Upsher-Smith's  
16 formulation is and Dr. Banker's position as to whether  
17 that formulation infringes the '743 patent.

18 JUDGE CHAPPELL: So, it's your position that  
19 the time on the record -- I guess the page and line  
20 cite that you're going to give to us should have been  
21 designated in camera pursuant to the rules we've been  
22 operating under.

23 MR. CURRAN: Correct, Your Honor.

24 JUDGE CHAPPELL: And complaint counsel does not  
25 object.

1 MR. NOLAN: Correct, Your Honor.

2 JUDGE CHAPPELL: Schering?

3 MR. LAVELLE: No objection, Your Honor.

4 JUDGE CHAPPELL: Okay, then I will so order it,  
5 and I'll request, Susanne, that you go ahead and  
6 designate that as soon as you have enough of a draft  
7 version or semi-final version so that we can designate  
8 the proper page and line numbers.

9 Now, what you might want to do is bring this up  
10 to me tomorrow after we have a better understanding of  
11 where it is in the record. Let's do that.

12 THE REPORTER: Can we go off the record for a  
13 minute?

14 (Discussion off the record.)

15 MR. NOLAN: Your Honor, we have also conferred  
16 about the fact that in the remaining portion that  
17 various pieces -- it's hard to exactly predict. There  
18 is risk that there may be a reference to in camera  
19 material, so it would be our joint request that for the  
20 remaining portion, which is not much, that we go in  
21 camera.

22 JUDGE CHAPPELL: Okay, then I will have to ask  
23 the public to leave the courtroom.

24 MR. LAVELLE: They have.

25 (The in camera testimony continued in Volume

1 22, Part 2, Pages 5367 through 5382, then resumed as  
2 follows.)

3 JUDGE CHAPPELL: Redirect?

4 MR. LAVELLE: Could I have just one minute,  
5 Your Honor, please?

6 JUDGE CHAPPELL: Yes, you may.

7 (Counsel conferring.)

8 MR. LAVELLE: No redirect, Your Honor. I would  
9 like to thank the Court and all of the parties for  
10 staying late to permit Dean Banker to get finished. We  
11 appreciate that.

12 JUDGE CHAPPELL: Thank you, Mr. Lavelle.

13 With that, we are adjourned until 9:30 tomorrow  
14 morning.

15 (Whereupon, at 6:15 p.m., the hearing was  
16 adjourned.)

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## 1 C E R T I F I C A T I O N O F R E P O R T E R

2 DOCKET/FILE NUMBER: 9297

3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

4 DATE: FEBRUARY 25, 2002

5

6 I HEREBY CERTIFY that the transcript contained  
7 herein is a full and accurate transcript of the notes  
8 taken by me at the hearing on the above cause before  
9 the FEDERAL TRADE COMMISSION to the best of my  
10 knowledge and belief.

11

12 DATED: 2/26/02

13

14

15

16 SUSANNE BERGLING, RMR

17

## 18 C E R T I F I C A T I O N O F P R O O F R E A D E R

19

20 I HEREBY CERTIFY that I proofread the  
21 transcript for accuracy in spelling, hyphenation,  
22 punctuation and format.

23

24

25 SARA J. VANCE

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